

Serial No. 09/554,387

Art Unit: 1617

In Paper No. 9, the Examiner rejects claims 11-12, 20-22 and 30 under 35 U.S.C. §102(b), as being anticipated by U.S. Pat. No. 3,865,939 of Jandacek ("Jandacek"). The Examiner contends that Jandacek teaches phytosterols (*i.e.*, phytostenols) as having hypocholesterolemic activity, and that phytosterols in conjunction with unsaturated C₆₋₁₈ fatty acids are useful as foodstuff additives for reducing serum cholesterol content in mammals. On the basis of this disclosure, the Examiner argues that Jandacek anticipates Applicant's claimed invention.

Applicant strenuously, but respectfully, traverses the Examiner's rejection, and the arguments and contentions set forth in support thereof, for the following reasons.

To begin with, it is well-settled that in order for a rejection under 35 U.S.C. §102(b) to be proper, each and every element of the claimed invention must be taught, either expressly or inherently, in a single prior art reference. (M.P.E.P. §2131).

One embodiment of Applicant's claimed invention is directed to methods of reducing serum cholesterol content in a mammal comprising: (i) providing a hypocholesteremic preparation comprising at least one component (a) selected from the group consisting of phytostenols and phytostenol esters *and* at least one component (b) selected from conjugated fatty acids having from about 6 to about 24 carbon atoms and glycerides of conjugated fatty acids having from about 6 to about 24 carbon atoms; and (ii) administering the hypocholesteremic preparation to a mammal in an amount effective to reduce serum cholesterol content in the mammal. Another embodiment of Applicant's claimed invention is directed to hypocholesteremic preparations comprising at least one component (a) selected from the group consisting of phytostenols and phytostenol esters *and* at least one component (b) selected from conjugated fatty acids having from about 6 to about 24 carbon atoms and glycerides of conjugated fatty acids having from about 6 to about 24 carbon atoms.

Each of the embodiments of Applicant's claimed invention specifies the use or inclusion of a conjugated fatty acid having from about 6 to about 24 carbon atoms and/or glycerides thereof. As is well-known, "conjugated", when referring to molecular bonds, as is the case in the instant application, means two or more double bonds with alternating single bonds,

Serial No. 09/554,387

Art Unit: 1617

such as is exemplified by the structure, $-\text{CH}=\text{CH}-\text{CH}=\text{CH}-\text{CH}=\text{CH}-$. (See, e.g., Hawley, G. (Ed.), The Condensed Chemical Dictionary, 10th ed., p.271, (Van Nostrand, New York, 1981, (a copy of which is enclosed for the Examiner's convenience); see also, Specification, page 4, lines 7-11).

Jandacek is directed to a process for the incorporation of "inherently nonabsorbable steroids", e.g., plant sterols, into edible oils through the use of a solubilizing agent. (Column 2, lines 28-35). Suitable solubilizing agents include free fatty acids, alkanols and esterified fatty acids. (Col. 4, lines 39-41). Suitable fatty acids may be saturated or unsaturated, and Jandacek specifically mentions "oleic acid" as an example of an unsaturated fatty acid, among a list of three other saturated fatty acids. (Col. 4, lines 51-52).

However, Jandacek fails to teach the use of conjugated fatty acids or esters thereof in conjunction with phytosterol(ester)s. The teaching in Jandacek that unsaturated fatty acids may be employed as solubilizing agents for "inherently nonabsorbable steroids" does not equate to teaching the use of conjugated fatty acids in accordance with Applicant's claimed invention. Moreover, the only exemplified unsaturated fatty acid, oleic acid, is not even polyunsaturated, and thus cannot be conjugated.

Thus, Applicant respectfully submits that Jandacek fails to anticipate either Applicant's claimed methods or compositions. Applicant respectfully requests withdrawal of the rejection based upon Jandacek.

In Paper No. 9, the Examiner rejects claims 11-12, 17, 20-22 and 27 under 35 U.S.C. §102(b), as being anticipated by Chemical Abstract No. 100:208354 of Hasegawa, synonymously identified and cited as "XP-002099834", (hereinafter referred to as "Hasegawa"). The Examiner contends that Hasegawa teaches linoleic acid and/or phytosterol (e.g., sitosterol) as being useful for lowering serum cholesterol in mammals. The Examiner also notes that Hasegawa teaches that vegetable oils have hypocholesterolemic effects "since they are high in linoleic acid and sitosterol. On the basis of this disclosure, the Examiner argues that Hasegawa anticipates Applicant's claimed invention.

Serial No. 09/554,387**Art Unit: 1617**

Applicant strenuously, but respectfully, traverses the Examiner's rejection, and the arguments and contentions set forth in support thereof, for the following reasons.

Once again, Applicant respectfully notes that the claimed invention is directed to methods and compositions using or including conjugated fatty acids. As indicated by the Examiner, Hasegawa teaches the use of linoleic acid with a phytosterol. The term linoleic acid refers to 9,12-octadecadienoic acid. The carbon-carbon double bonds are separated by two methylene groups. In other words, it is not a conjugated fatty acid. Conjugated linoleic acid ("CLA") is specifically referred to as "conjugated" linoleic acid. Linoleic acid would have to be converted to conjugated linoleic acid by synthetic and/or fermentation mechanisms. Hasegawa contains no such teaching. Thus, the use of linoleic acid and vegetable oils in Hasegawa does not equate to a teaching of conjugated fatty acids and phytosterol(ester)s.

Thus, Applicant respectfully submits that Hasegawa fails to anticipate either Applicant's claimed methods or compositions. Applicant respectfully requests withdrawal of the rejection based upon Hasegawa.

In Paper No. 9, the Examiner rejects claims 13-16, 18-19, 23-26 and 28-29 under 35 U.S.C. §103(a), as being unparentable over Jandacek and Hasegawa, in view of European Patent Application No. EP 0594612 of Miettinen, *et al.* ("Miettinen") and U.S. Pat. No. 5,277,910 of Hidvégi ("Hidvégi"). The Examiner argues that Jandacek and Hasegawa teach the claimed invention, as set forth in relation to the rejections under 35 U.S.C. §102(b) described above, except that the Examiner acknowledges the failure of Jandacek and Hasegawa to teach carboxylic acid esters of phytosterol compounds, wherein said carboxylic acid contains from 2 to 22 carbon atoms and up to 3 double bonds. The Examiner also notes that neither Jandacek, nor Hasegawa, teaches the encapsulation of the compositions taught therein within a gelatin.

The Examiner argues that Miettinen and Hidvégi cure the deficiencies of Jandacek and Hasegawa. Specifically, the Examiner contends that Miettinen teaches the use of phytosterol fatty acid esters based upon rapeseed oil in lowering cholesterol, and that rapeseed oil contains a large amount of unsaturated fatty acids. The Examiner further contends that

Serial No. 09/554,387
Art Unit: 1617

Hidvégi teaches the use of fatty acids such as linoleic acid in conjunction with sitosterol, in the form of a gelatin capsule, for lowering blood-lipid levels.

The Examiner argues that based upon these teachings, the claimed invention would have been obvious to one of ordinary skill in the art. Applicant strenuously, but respectfully, traverses the Examiner's rejection and the arguments and contentions in support thereof, as explained in more detail below. Initially, it is respectfully submitted that the Examiner has failed to establish a *prima facie* case of obviousness based upon the cited references.

It is well-settled that in order to establish a *prima facie* case of obviousness, and thus shift the burden of proving non-obviousness onto Applicant, the Examiner must show all of the following three criteria: (1) there must be some suggestion or motivation to modify or combine the references as suggested by the Examiner (it is not sufficient to say that the cited references can be combined or modified without a teaching in the prior art to suggest the desirability of the modification); (2) there must also be a reasonable expectation of success; and (3) the references as combined must collectively teach or suggest all limitations of the claims. The teaching or suggestion to combine and modify the cited art and the reasonable expectation of success must both be found in the prior art and not in the Applicant's Specification. (M.P.E.P. §2143).

None of the three criteria necessary to establish such a *prima facie* case of obviousness has been satisfied.

Applicant submits that none of the cited references, nor a combination thereof, teaches or suggests each and every element of the claimed invention. Specifically, none of the cited references teaches the use of conjugated fatty acids in lowering serum cholesterol levels. Moreover, none of the cited references teaches the use of a phytosterol compound with a conjugated fatty acid for such a purpose. Miettinen does disclose the use of rapeseed oil. Applicant notes that rapeseed oil does contain a large amount of unsaturated fatty acids. The polyunsaturated fatty acids in most rapeseed oils are 9,12 and 9,12,15 isomers of linoleic and linolenic acids. The disclosure of rapeseed oil does not equate to the disclosure of conjugated

Serial No. 09/554,387**Art Unit: 1617**

fatty acids. With respect to Hidvégi, Applicant notes that linoleic acid is not the same as conjugated linoleic acid, as explained above. Moreover, Hidvégi does not teach the use of sitosterol and linoleic acid. Hidvégi simply notes that the disclosed starting material (*i.e.*, alfalfa) is known to contain some amount of both sterols and fatty acids, such as linoleic.

Secondly, Applicant submits that none of the cited references, either alone or in combination, contains a teaching or suggestion which would motivate one of ordinary skill in the art to combine and modify their teachings, as suggested by the Examiner, in order to arrive at the claimed invention. As discussed above, none of the cited references teaches the use of conjugated fatty acids. Absent any specific teaching to use conjugated fatty acids, it cannot reasonably be said that one of ordinary skill in the art would be motivated to modify the references to include their use.

Finally, given the lack of any teaching or suggestion to use conjugated fatty acids in conjunction with phytosterol compounds, and given the lack of any teaching or suggestion motivating such a modification of the prior art, one of ordinary skill in the art would not have a reasonable expectation of successfully achieving Applicant's claimed invention, based upon the cited art.

Accordingly, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness, as none of the three criteria necessary to establish a *prima facie* case of obviousness has been satisfied. Thus, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §103(a).

Even if it were assumed, for argument's sake, that a *prima facie* case of obviousness could be established based upon the cited references and that such a *prima facie* case of obviousness had been established, which it cannot and has not, any such alleged *prima facie* case of obviousness would be overcome by Applicant's showing of unexpected synergism between the phytosterol(ester)s and the conjugated fatty acids. As evidenced by the Examples set forth in Applicant's Specification, beginning at page 8, line 17, the combination of phytosterol(ester)s and conjugated fatty acids in accordance with Applicant's invention perform better than either component alone in reducing serum cholesterol levels. As can be seen from

Serial No. 09/554,387**Art Unit: 1617**

Table 1, at page 9, the combinations decrease the serum cholesterol levels in amounts greater than either component alone.

It is submitted that Applicant's showing of synergism sufficiently rebuts any alleged *prima facie* case of obviousness. Therefore, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

In view of the remarks set forth above, Applicant submit that all pending claims patentably distinguish over the prior art of record and known to Applicant, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejections and a Notice of Allowance are respectfully requested.

Respectfully submitted,

BERND FABRY

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(Date)

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Enclosure: Hawley, G. (Ed.), The Condensed Chemical Dictionary, 10th ed., p. 271, Van Nostrand, New York, 1981